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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,956	02/08/2001	Peter James Woolf	A0000133-01-CA	5820
909	7590	03/24/2004	EXAMINER	
PILLSBURY WINTHROP, LLP P.O. BOX 10500 MCLEAN, VA 22102			MARSCHEL, ARDIN H	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/778,956

Applicant(s)

WOOLF ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' arguments, filed 1/9/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

NEW MATTER IN THE SPECIFICATION

The amendment, filed 1/9/04, is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: On page 11, lines 5-20, a paragraph was replaced with a paragraph containing the addition of Serum "to ensure a proper growth environment". This replaced a sentence wherein serum was described as being added to cells for the purpose wherein it causes a treatment which "may be emulated" by said serum. Thus the serum addition is emulating a treatment as filed whereas the newly amended sentence now ensures a "proper growth environment". The concept of a proper growth environment is vastly different from emulating a treatment. A treatment, for example, may not support any growth, for example. Also a proper growth environment may merely be an environment wherein the cells grow and not viewed as a treatment. The differences between the present disclosure regarding serum addition to cells and the prior wording therefore supports this NEW MATTER

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rejection due to the differences therebetween. This rejection is necessitated by amendment.

Applicant is required to cancel the new matter in the reply to this Office Action.

NON-STATUTORY SUBJECT MATTER

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

This rejection is maintained and reiterated from the previous office action, mailed 9/9/03, and as necessitated by amendment regarding newly added claim 23. Applicants argue that the MPEP describes statutory processes or systems that require measurements of physical objects or activities to be transformed outside of the computer. Applicants go on to argue that this is the case for the instant claims via the receiving of data for expression from control and treatment sets of cell-derived samples as crisp input data. In response the receiving of data does not cite or require the transformation of measurements of physical objects or activities outside of the computer. It is only data receiving. Thus, this safe harbor is not present in the instant claims. Applicants then argue that the claims recite operating on real-world values. This is deemed data manipulation and again does not "require" any outside of the computer measurements per se. Applicants then argue that page 11 of the specification cites transforming isolated RNA from cells into sets of data usable in the instant claims. This argument is also non-persuasive as this transformation requirement

is not claimed. Applicants then argue to step back from the MPEP guidelines to argue that the manipulation of expression profiles can generate voluminous data sets that are not amenable to ordinary methods of analysis and thus the instant claims are useful in such processing. In response the extent of data manipulation voluminousness does not move the practice out of the view that it is still data manipulation and thus non-statutory. The examples in the MPEP support the concept of usefulness as being directed to some type of physical transformation and not merely data manipulation.

VAGUENESS AND INDEFINITENESS

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained and reiterated from the previous office action, mailed 9/9/03. Applicants argue that the claims recite what they recite. In response the claims are rejected for what they recite as being vague and indefinite. This vagueness and indefiniteness is not based on whether the preamble should or should not be given weight. It instead is based on a conflict between the metes and bounds of the preamble and the actually recited claim steps as to which part of the claims determine the metes and bounds thereof. Applicants also argue that they may claim what they regard as their invention. This is acknowledged, however, a rejection may be properly set forth if the invention as claimed is supportive of such a rejection as is the case here regarding vagueness and indefiniteness. Applicants also argue that "differential expression analysis" itself is not the applicants' invention. This conflicts directly with the preamble

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of claim 1, for example, wherein the claimed method is directed to managing and analyzing information obtained from differential expression. If this is not what applicants' invention is then what is meant by claiming it as such? Applicants then argue that the examiner is merely wondering whether the preamble should be given weight or not. In response this rejection is not based on wondering but is based on a conflict in the claims regarding what controls the metes and bounds of the claims thus supporting this rejection based on vagueness and indefiniteness. Applicants then allege that a case-by-case basis analysis is to be made on whether the preamble limits the scope of the claims or not. Given a case-by-case basis, this case supports the rejection based on the above described conflicting metes and bounds recitations in the claims. Applicants proposed a personal interview if any issue remains on this topic. In response applicants are advised that arranging an interview may be obtained via calling the examiner at the telephone number set forth at the end of this action, if desired. Applicants lastly described amending the claims for readability. The claim amendments have been reviewed and do not eliminate the basis for this rejection.

No claim is allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

March 19, 2004

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER 3/19/04